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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	PAPER NUMBER
3738	14

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Applicati n No.	Applicant(s)	
	09/963,848	FRENCH ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *24,26-33,36,42-44,46,47,50-86,90-92,94 and 95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,25,34,35,37-41,45,48,49,87-89 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *10 January 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, subspecies (1)(b), (2)(a), (3)(a), (4)(b), (5)(a), (6)(b)(ii) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that no undue burden exists for any search for examination of each of the species and that the requirement by the Office that Applicant select a sub-species across each of the species indicates that they are not mutually exclusive. This is not found persuasive because the *sub-species* are mutually exclusive, and therefore warrants the election of sub-species requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-95 are currently pending, of which claims 91-92 have been withdrawn for being drawn to a non-elected Group of a method of reinforcing the pericardium. Claim 1 is currently generic. Claims 24, 26-33, 36, 42-44, 46, 47, 50-86, 90, 94 and 95 have also been withdrawn from consideration for the following reasons:

a) Claims 24 and 36, drawn to non-elected sub-species (4)(a) of a woven surface material.

b) Claims 26-33, drawn to non-elected sub-species (5)(b)(i-iii)-(5)(c) of mechanical linkage.

c) Claims 42-44 and 90, drawn to non-elected sub-species (3)(b)-(3)(d) of size adjusters.

d) Claims 46-47, drawn to non-elected sub-species (1)(c), (1)(f), (1)(j) of device configuration.

e) Claims 50-54 and 94, drawn to non-elected sub-species (1)(i) of device configuration.

f) Claims 55-86 and 95, drawn to non-elected sub-species of device configuration. The elected sub-species (1)(b) of Figure 8 is not disclosed as comprising at least one rib.

3. The claims being considered for further examination on the merits are 1-23, 25, 34, 35, 37-41, 45, 48, 49, 87-89 and 93.

Drawings

4. The amendment to the drawings filed 1/10/02 has been entered as Paper No. 11, and the changes to the drawings have been approved by the Examiner. The formal drawings filed 1/10/02 have been entered as Paper No. 12.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "radio-opaque markers (380)", as mentioned on page 20, line 1, should be shown in Figure 21 and "xiphoid process (510)", as mentioned on page 21, line 4, should be shown in Figure 22A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference sign "202" shown in Figure 8 is not mentioned in the specification. Examiner suggests mentioning it in [0064]. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: on page 5, line 5, it appears that "hyalonurate" should be changed to --hyaluronate--.

Appropriate correction is required.

Claim Objections

8. Claims 16 and 39 are objected to because of the following informalities:

a) Claim 16, line 2, it appears that "hyalonurate" should be changed to --hyaluronate--.

b) Claim 39 is repeating elements already mentioned in claim 35, on which it depends. Examiner suggests changing "the compliant and substantially non-elastic member comprises an inner member laminated to an outer member" to --the inner member is laminated to the outer member--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 89 recites the limitations "the needle" and "the introducer" in line 2. There is insufficient antecedent basis for these limitations in the claim. It appears claim 89 should be dependent on claim 88 rather than on claim 87.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

cancelled

12. Claim 93 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A pericardium is part of the human body, and therefore, is non-statutory subject matter.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-6, 12-15, 18, 23, 25, 34, 35, 37-41, 45, 48, 49, 87-89 and 93 are rejected under 35 U.S.C. 102(e) as being anticipated by Snyders (USPN 6,095,968).

Snyders discloses a pericardial reinforcement with all the elements of claim 1. See Figure 2 for the pericardial reinforcement (10) comprising a substantially non-elastic (column 2, line 15) member (combination of 12 and 13) having an interior surface (interior surface of 13) for placement adjacent an epicardium, the interior surface tending to inhibit adhesions with the epicardium (columns 3-4, lines 65-4) and having an exterior surface (exterior surface of 12) which is capable of being attached to the inside of a pericardium (column 3, lines 5-17). The

phrase "for attachment" is functional language, so the claim only requires that the exterior surface be *capable* of being attached to the inside of a pericardium.

Claims 2-6, see column 4, lines 1-4 and Figure 5 for the interior surface comprising a lubricious polymeric (column 3, lines 24-27) material, wherein the friction-reducing coating on the interior surface and steroid dispersion inherently resist ingrowth with the epicardium.

Claims 12-15, 18, 23 and 34, see column 3, lines 7-17 and column 4, lines 60-63 for exterior surface being of woven Dacron (polymeric), which by nature promotes endothelialization, allows for ingrowth into, attachment to, and adherence with the pericardium.

Claim 25, see Figure 2 for exterior surface material comprising a non-woven (16) polymeric material (column 5, lines 14-21).

Claims 35 and 37-41, see column 3, lines 1-17 and columns 4-5, lines 60-21 for compliant and substantially non-elastic member comprising an inner member (13) and an outer member (12) of separate layers of woven or non-woven fabrics laminated together at their margins, the outer member comprising a non-woven fabric (16).

Claim 45, see Figure 2 for band (5).

Claims 48 and 49, see Figure 5 and column 2, lines 19-23 for sack having a closed end.

Claims 87-89, see columns 2-3, lines 55-1 and column 6, lines 60-65 for method of reinforcing the pericardium.

Claim 93, see Figure 5 for a pericardium reinforced with the compliant pericardial reinforcement of claim 1.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 7-9, 11 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders in view of Alferness (USPN 6,241,654 as cited in applicant's IDS).

Snyders discloses a pericardial reinforcement with all the elements of claim 1, but is silent to the interior surface being the fluorocarbon polymers PTFE or ePTFE or the polymer polypropylene, as required by claims 7-9 and 11, and the exterior surface being polyethylene terephthalate or ePTFE, as required by claims 19-21. Alferness teaches a cardiac reinforcement device that can be placed under the parietal pericardium (column 10, lines 31-33) made of PTFE, ePTFE, polypropylene or polyethylene terephthalate (polyester) because these materials are physiologically inert to minimize an immune reaction or other excessive inflammatory response. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness to modify the pericardial reinforcement of Snyders by making the interior surface of PTFE, ePTFE or polypropylene and the exterior surface of ePTFE or polyethylene terephthalate (polyester) because these material are well known in the art to be physiologically inert and minimize an immune reaction or other excessive inflammatory response. See columns 6-7, lines 62-2.

17. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders and Alferness as applied to claims 7, 19 and 21 above, and further in view of Martakos et al. (USPN 5,897,587).

Snyders, as modified by Alferness, discloses a pericardial reinforcement with all the elements of claim 7, but is silent to the interior and exterior ePTFE surfaces having internodal spacings of less than about 40 microns and greater than about 60 microns, respectively, as required by claims 10 and 22, respectively. Martakos et al. teaches a multistage PTFE prosthesis wherein one section has an internodal spacing of less than about 40 microns in order to prevent encapsulation and another section has an internodal spacing of greater than about 60 microns in order to allow for tissue ingrowth during healing. See column 3, lines 3-20. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Martakos et al. to modify the pericardial reinforcement of Snyders and Alferness by making the interior surface have an internodal spacing of less than about 40 microns in order to further prevent encapsulation of the surface, which already has coating that inhibits ingrowth with the epicardium. It would have been obvious to make the exterior surface have an internodal spacing of greater than about 60 microns in order to allow for tissue ingrowth with the pericardium to strengthen the attachment therebetween.

18. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyders in view of Williams et al. (USPN 5,131,907).

Snyders discloses a pericardial reinforcement with all the elements of claim 1, but is silent to the material promoting endothelialization comprising an effective hyaluronate salt or an

angiogenic material, as required by claims 16 and 17, respectively. Williams et al. teaches that it is old and well known in the art to use fibronectin hyaluronate for adhering fibroblasts to an implant by citing Laterra et al. See column 7, lines 9-11. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to Williams et al. for the disclosure of using hyaluronate for adhering cells to an implant as being old and well known the art in order to modify the pericardial reinforcement of Snyders by using appropriate hyaluronate to promote endothelialization. Williams et al. also teaches treating an implant substrate material with collagen (angiogenic material) in order to improve human endothelial cell adhesion. See column 7, lines 37-42. It would have been obvious to one of ordinary skill in the art to look to the teachings of Williams et al. to modify the pericardial reinforcement of Snyders by including into the exterior surface the angiogenic material collagen in order to improve human endothelial cell adhesion. Promoting endothelialization will increase the strength of attachment between the pericardial reinforcement and the pericardium.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

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